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EXAMINER	
HALVORSON, MARK	

ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/564,823	Applicant(s) STEIN ET AL.	
	Examiner Mark Halvorson	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
 4a) Of the above claim(s) 1-9, 14-19, 21-38, 40 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 20, 39 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/18/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-42 are pending.

Election/Restrictions

Applicant's election without traverse of Group IV, claims 20, 39 and 41 in the reply filed on October 11, 2007 is acknowledged. Claims 1-9 14-19, 21-37, and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 38 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected linked invention.

Linking claims 10-13 and elected claims 20, 39 and 41 are under examination.

Objections to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 23, line 4. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 20, 38, and 41 are objected to because they depend on a non-elected claim. The claims are objected to because claim 20 depends on claim 1, a non-elected claim, claim 39 depends from claim 3, a nonelected claim and claim 41 depends from claim 9, a nonelected claim. For examination purposes the limitation of the claims from which the examined claim depends will be incorporated into the examined claims. However, this does not relieve applicants the burden of incorporating the limitations into the respective examined claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20, 39 and 41 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 20, 39 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 39 are rejected for having a broad range or limitation together with a narrow range or limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by

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such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation "wherein said tumour disease is metastasizing", and the claim also recites "in particular is metastasising colon cancer" which is the narrower statement of the range/limitation. In the present instant claim 39 recites "use of an oligonucleotide according to claim 3" wherein the olinucleotide of claim 3 is an "oligonucleotide, which specifically hybridizes to a nucleic acid sequence according to claim 1, in particular according to SEQ ID No:7" which is the narrower statement of the range/limitation.

Claims 20, 39 and 41 are rejected because claims 20, 39 and 41 provide for the use of a nucleic acid, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For compact prosecution, the claims are interpreted as reading on a method for diagnosing tumour disease comprising determining the expression of the nucleic acid of SEQ ID NO:1 in a biological sample from a pathologic tissue or bodily fluids and comparison of said expression with the expression of the nucleic acid of SEQ ID NO:1 in a healthy tissue or bodily fluid.

Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: wherein an increase in the expression of 7a5/prognostin is indicative of colon carcinoma.

Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. The phrases "specifically hybridizes to" is indefinite because it is not clear what is meant by these terms. To overcome this rejection the conditions for the hybridization, including the wash step, must be incorporated into claim 39, provided written support for such an amendment exists.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 20, 39 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the diagnosis of colon cancer, wherein said colon cancer is metastasizing, comprising the step of determining the expression of 7a5/Prognostin in a biological sample from a pathologic tissue and comparison of said expression with the expression of 7a5/Prognostin in a healthy tissue, does not reasonably provide enablement for a method for the diagnosis of tumour diseases, wherein said tumour disease is metastasizing, comprising the step of determining the expression of 7a5/Prognostin in a biological sample from a pathologic tissue or bodily fluids and comparison of said expression with the expression of 7a5/Prognostin in a healthy tissue or bodily fluid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are drawn to a method for the diagnosis of tumour diseases, comprising the step of determining the expression of 7a5/Prognostin in a biological sample from a pathologic tissue or bodily fluids and comparison of said expression with the expression of 7a5/Prognostin in a healthy tissue or bodily fluid.

The specification discloses that the expression of 7a5/Prognostin in primary colon tumors correlates with the development of metastasis. (Fig 2). The specification further discloses that the expression of 7a5/Prognostin in primary colon tumours was predictive of metastasis free survival (page 28 4th paragraph to page 29, 1st paragraph). The specification does not disclose that the expression of 7a5/Prognostin was elevated in any other cancer other than colon cancer nor was the expression of 7a5/Prognostin predictive of metastatic spread in any other cancer other than colon cancer. In addition the specification does not disclose the expression of 7a5/Prognostin in bodily fluids.

One cannot extrapolate the teaching of the specification to the scope of the claims because the specification does not provide examples and guidance for diagnosing any other cancer than colon cancer and does not provide any examples and guidance for detecting the expression of 7a5/Prognostin in a biological sample in a bodily fluid.

The role of the 7a5/Prognostin in cancer appears to be unclear. Based on the disclosure of the instant application could be inferred that 7a5/Prognostin is a novel target for further research. MPEP 2164.04 [R-1], citing *Genentech v. Wellcome Foundation*, 29 F. 3d 1115, 1563-31, USPQ2d 1161, 1167-68 (Fed. Cir. 1994), states that "Nascent technology, however, must be enabled with a specific and useful teaching." The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology."

Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker to successful clinical application. Tockman et al teach that prior to the successful application of newly described markers, research

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must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and **if validated** can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease. This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point marker (p. 2714, see Biomarker Validation against Acknowledged Disease End Points). Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2). In addition, Slamon et al. (Science Vol. 235, January 1987, pages 177-182) teach other essential factors that are known to be important in the prognosis of breast cancer in individual patients such as size of the primary tumor, stage of the disease at diagnosis, hormonal receptor status, and number of axillary lymph nodes involved with disease (page 178, 1st column, 2nd paragraph). Such data are critical to assessing actuarial curves for relapse (Figure 3), and for comparing disease-free survival and overall survival to prognostic factors (Table 4). It is clear that the art teaches the necessary experimentation and data required to allow one of skill in the art to predict that the expression of 7a5/Prognostin could be used to diagnose any cancer and predict the metastatic spread in any cancer. The specification has not provided guidance or examples to disclose that the expression of 7a5/Prognostin was elevated in any other cancer other than colon cancer.

In particular, cancers comprise a broad group of malignant neoplasms divided into two categories, carcinoma and sarcoma. The carcinomas originate in epithelial

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tissues while sarcomas develop from connective tissues, see Taber's Cyclopedic Medical Dictionary (1985, F.A. Davis Company, Philadelphia, p. 274). Given that not all cancers originate from the same tissue types, it is expected and known that cancers originate from different tissue types have different structures as well as etiologies and would present differently. Thus, it would not be predictably expected that a nexus, for example drawn to a connection between AXL, breast and prostate cancer, and cancer invasivity, would be established between cancer types that arose from different tissue types. Further, it is well known that even two carcinomas that present on the same organ have significant differences in etiology and genetic constitution. For example, Busken, C et al, (Digestive Disease Week Abstracts and Itinerary Planner, 2003, abstract No: 850), teach that there is a difference in COX-2 expression with respect to intensity, homogeneity, localization and prognostic significance between adenocarcinoma of the cardia and distal esophagus, suggesting that these two cancers have different etiology and genetic constitution (last five lines of the abstract). Additionally, Kaiser (Science, 2006, 313, 1370) teaches that in a genomic analysis of mutations in breast and colon cancers, it was found that the cancer genes differ between each colon and breast cancers and each tumor had a different pattern of mutations. Kaiser teaches that the steps to cancer may be more complex than had been anticipated, see 3rd col. Furthermore Krontiris and Capizzi (Internal Medicine, 4th Edition, Editor-in-chief Jay Stein, Elsevier Science, 1994 Chapters 71-72, pages 699-729) teach that the various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocols. Chemotherapeutic agents are frequently useful against a specific type of neoplasm and especially with the unpredictability of the art there are no drugs broadly effective against all forms of cancer, see Carter, S. K. et al. Chemotherapy of Cancer; Second edition; John Wiley & Sons: New York, 1981; appendix C. Given the above, it is clear that it is not possible to predictably extrapolate a correlation between 7a5/Prognostin in any tumor type other than colon cancer, based on the information in the specification and known in the art without undue experimentation.

Given the disclosure of the specification and teaching in the art, one of skill in the art could not predictably determine that the overexpression of 7a5/Prognostin would be predictive of any tumour disease.

In addition, the specification does not disclose that the expression of 7a5/Prognostin could be determined in a biological sample from a bodily fluid. The specification does not disclose the expression of 7a5/Prognostin in bodily fluids. Further, 7a5/Prognostin appears to be a novel molecule with no information in the art on the expression and function of 7a5/Prognostin.

Given the disclosure of the specification and teaching in the art, one of skill in the art could not predictably determine that the overexpression of 7a5/Prognostin could be determined in a biological sample from a bodily fluid.

Therefore, in view of the breadth of the claims, lack of guidance in the specification, the absence of working examples, and the state of the art, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

Claims 20 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 20 and 41 are drawn to a genus of nucleic acids having a sequence comprising nucleic acid derivatives of SEQ ID NO:1, nucleic acids that code for polypeptides with 80% homology with SEQ ID NO:2 and a nucleic acid that displays polymorphisms of 7a5/Prognostin.

The specification discloses only one nucleic acid, the nucleic acid of SEQ ID NO:1.

The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written

description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *Id.* At 1567, 43 USPQ2d at 1405. The court concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.*

The Federal Circuit has recently clarified that a molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Id.* At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of the genus of nucleic acids, per Lilly by structurally describing a representative number of p28ING5 tumor suppressor proteins that function as claimed or by describing structural features common to the members of the genus, which features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe the genus of nucleic acids in a manner that satisfies either the Lilly or Enzo standards. There are insufficient structural features common to all members of the genus of nucleic acids. The genus of nucleic acids includes nucleic acid derivatives of SEQ ID NO:1, nucleic acids that code for polypeptides with 80% homology with SEQ ID NO:2 and a nucleic acid that displays polymorphisms of 7a5/Prognostin. The term “derivative” is not defined in the specification and is interpreted to encompass a broad range of nucleic acids. The

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number of nucleic acids that code for polypeptides with 80% homology with SEQ ID NO:2 also encompasses a large number of nucleic acids with distinct sequences. The specification and the art does not indicate any polymorphisms of 7a5/Prognostin. Thus, the number of nucleic acids that fit this subgenus is unknown. In any event, Applicants were not in possession of the claimed nucleic acids that displays polymorphisms of 7a5/Prognostin. The claimed genus of nucleic acids encompasses a vast number of nucleic acids, only one of which is identified in the instant specification. One species of nucleic acids, the nucleic acid of SEQ ID NO:1, does not meet the standard set forth in Lilly.

The instant specification may also provide an adequate written description of the genus of nucleic acids if the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. The specification discloses only one species of nucleic acids, the nucleic acid of SEQ ID NO:1. Thus, the specification does not describe sufficient structural characteristics that correlate with the ability of the genus of nucleic acids to function as contemplated by the specification and for the reasons set forth above do not meet the standards set forth by Enzo.

Thus, the specification does not provide an adequate written description of the genus nucleic acids of claims 20 and 41 that is required to practice the claimed invention. Applicants have not described the genus of nucleic acids sufficiently to show they had possession of the claimed genus of nucleic acids .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20, 39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayer Corp. (WO 02/29086, published April 11, 2002).

Claim 39 is drawn to a method of diagnosing colon cancer comprising determining the expression of an oligonucleotide that hybridizes to the nucleic acid of SEQ ID NO:1 in a biological sample from a pathologic tissue and comparison of said expression with the expression of an oligonucleotide that hybridizes to the nucleic acid of SEQ ID NO:1 in a healthy tissue.

Claims 20 and 41 are drawn to a method of diagnosing colon cancer comprising determining the expression of a derivative of the nucleic acid of SEQ ID NO:1 in a biological sample from a pathologic tissue and comparison of said expression with the expression of a derivative of the nucleic acid of SEQ ID NO:1 in a healthy tissue.

Bayer claims a method of diagnosing colon cancer comprising determining the expression of a nucleic acid that has a 354 base pair nucleic acid sequence that has 100 sequence identity to a 354 base pair sequence of SEQ ID NO:1 in a biological sample from a pathologic tissue and comparison of said expression with the expression of the nucleic acid in a healthy tissue. (claim 2, also see sequence comparison). Burgess et al's nucleic acid would likely hybridize to the nucleic acid of SEQ ID NO:1 especially considering the exact hybridization conditions were not specifically defined in the specification and are not listed in the claim. Also, for examination purposes, Burgess's nucleic acid is considered a derivative of the nucleic acid of SEQ ID NO:1.

Summary

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone

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number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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